

REMARKS

Claims 20-32 are pending in this application. Claims 27-32 have been withdrawn as being directed to non-elected subject matter, in view of the Restriction Requirement imposed in the Office Action mailed September 27, 2005.

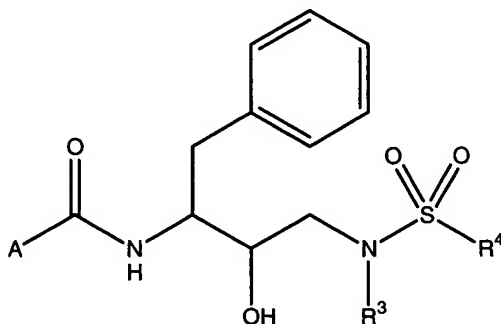
Restriction Requirement under 35 U.S.C. §121 and Election of Species

i) Election

The Office Action has imposed a restriction requirement among the compounds of Group I (claims 20-26), Group II (claims 27-31) and Group III (claim 32). This restriction requirement acknowledges that the subject matter of Groups I, II, and III constitute separately patentable inventions. MPEP § 806.04(h).

In response, Applicants elect the invention of Group I and traverse the Restriction Requirement insofar as it applies to Groups I and III.

Claim 20 of Group I recites a compound represented by the formula:

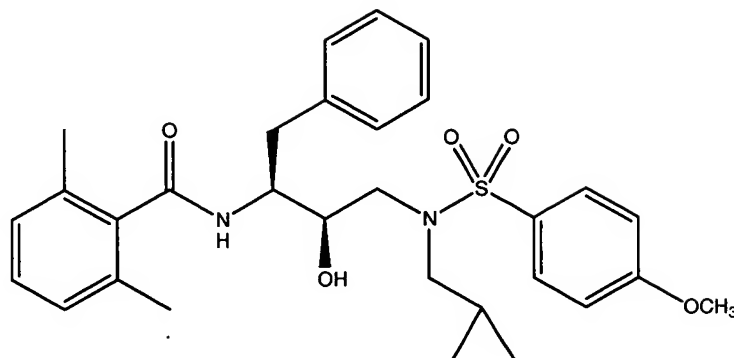


or a pharmaceutically acceptable salt thereof, wherein A, R³, and R⁴ are as defined in claim 1.

Applicants hereby elect the following species for examination:

N-[2R-hydroxy-3-[[4-methoxyphenyl)sulfonyl](2-methylpropyl)amino]-1S-(phenylmethyl)propyl]-2,6-dimethyl benzamide

This compound has the structure



and is a compound of claim 20, wherein A is 2,6 dimethylphenyl (an aryl radical that is disubstituted with alkyl, as claimed), R³ is 2-methylpropyl (an alkyl radical, as claimed), and R⁴ is 4-methoxyphenyl (an aryl radical¹, as claimed).

The elected species is described at page 30 (see Example 10B) with respect to its synthesis and further described at page 138 (see Table 5A, entry 15) with respect to its molecular formula, its calculated molecular weight, and its measured molecular weight. The elected species is additionally described at page 185 (see Table 21, entry 32) with respect to its measured retroviral protease inhibitory activity (IC₅₀), biological efficacy (EC₅₀), and cell toxicity (TD₅₀).

All claims 20-26 of Group I read on this elected species.

ii) Compounds Embracing the Elected Species and within the Same Inventive Concept

Page 2 of the Office Action states

. . . upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice).

In response, Applicants respectfully submit that the entire scope compounds embraced by claim 20, is within the same “inventive concept.” This is evidenced by the issuance of related

¹ As defined on page 19, lines 20-22 of the specification, the term “aryl” embraces phenyl that is substituted with alkoxy (*e.g.*, methoxy)

U.S. Patent Nos. 6,455,581 and 6,060,476, having claims of comparable or even broader scope than the now-pending elected claims of Group I. As such, claims 20-26 are directed to a single invention and should be examined without restriction among Markush group members.

In particular, now that Applicants have complied with the election of species requirement, they are entitled to full examination on the merits of elected claims 20-26 of Group

I. According to MPEP § 803.02, in Markush claim practice,

...the examiner may require a provisional election of a single species prior to examination on the merits. ...Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration. (emphasis added).

....

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a *non-elected species*, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration.

Furthermore, MPEP § 803.02 states, “[I]t is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention.” (emphasis added). Unity of invention is based on well-settled judicial precedent. For example, the MPEP cites *In re Harnisch* and *Ex parte Hozumi*. 206 U.S.P.Q. 300 (C.C.P.A. 1980) and 3 U.S.P.Q.2d 1059 (Bd. Pat. App. & Int. 1984). In *Harnisch*, the Court of Customs and Patent Appeals rejected the imposition of a restriction requirement in a Markush-type claim where all of the compounds had a single use, and thus had unity of invention. Likewise, in *Hozumi*, the Board of Patent Appeals and Interferences (hereinafter “Board”) reversed a rejection

of a Markush-type claim, where the compounds were core structures having plural diverse pendant moieties.

Other decisions reinforce the proposition that unity of invention is based on a common utility. For example, in *In re Jones*, the Court of Customs and Patent Appeals reversed the Board's 'improper Markush group' rejection precisely because the claimed compounds had a common function. 162 F.2d 479, 74 U.S.P.Q. 149 (C.C.P.A.1947). In *Ex parte Dahlen*, 42 U.S.P.Q. 208 (Bd. App. 1938), the Board permitted claims to compounds having a common core with pendant widely-varying side chains, because the claimed compounds had common properties.

Based on the above decisions, claims 20-26 have unity of invention, because these claims embrace a single inventive concept. The compounds of these claims are retroviral protease inhibitors. These have a single common core and pendant moieties, as set forth in the definitions of A, R³, and R⁴. No matter which combination of pendant moieties is selected, the resulting compound is a retroviral protease inhibitor. Such compounds may also have other uses, but all are retroviral protease inhibitors. To restrict claims 20-26 to any scope less than their full scope is contrary to established precedent and M.P.E.P. guidance.

iii) Rejoinder of Process Claims 27-31 (M.P.E.P. § 821.04)

Applicants have elected product claims. Moreover, the process claims 27-31, by virtue of their dependency on the elected product claims, are of the same scope and therefore comply with the requirements under M.P.E.P. § 821.04 for rejoinder. Upon a finding that the elected product claims are allowable, the process claims must be rejoined. See M.P.E.P. § 821.04.

Applicants therefore respectfully request, upon a finding that the elected product claims are allowable, (1) withdrawal of requirement for restriction between Groups I and II and (2)

rejoinder of withdrawn process claims 27-31.

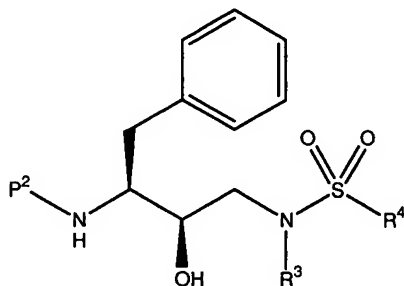
iv) Arguments Traversing the Requirement for Restriction between Groups I and III

The Office Action at page 5 requires restriction between Groups I and III because

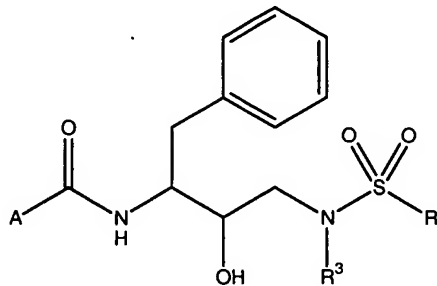
Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 806.01).

The Office Action offers no reasoning as to why the above criteria for “unrelated inventions” would apply to Groups I and III. Instead, restriction is imposed because “in the instant case the different inventions are products that could fall into different classes and subclasses based upon the election of species.” Applicants respectfully submit that restriction cannot be based merely on the existence of several possible classes and subclasses which might embrace the claimed compounds.

The inventions of Groups I and III are clearly related. In particular, P¹ is hydrogen in the generic formula recited in claim 32 (Group III). This claim and claim 20 (Group I) are therefore directed to compounds represented by the following formulas:



Claim 32, Group III



Claim 20, Group I

wherein P² of claim 32 (Group III) can be a number of possible radicals, such as aroyl, that result in a carbonyl (C=O) group being bonded to the left-hand nitrogen atom, as in claim 20 (Group I).

In view of the above, rejoinder of claim 32 with the elected invention of Group I is respectfully requested.

CONCLUSION

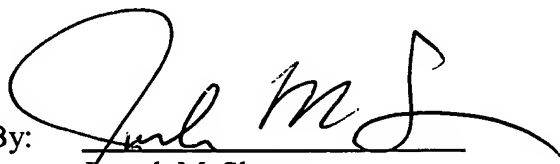
In summary, Applicants have now elected a species, in response the restriction requirement imposed in the Office Action. MPEP § 803.02 requires full examination of claims reading on the elected species. Restriction of claims 20-26 to any scope less than their full scope is improper.

Accordingly, in view of the above amendments and remarks, rejoinder of claim 32 with the elected claims 20-26 and prompt and favorable consideration of claims 20-26 and 32 on the merits is earnestly solicited.

Respectfully submitted,

Date: October 27, 2005

By:

A handwritten signature in black ink, appearing to read 'Joseph M. Skerpon', written over a horizontal line.

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